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Ingrid A. Beattie
Mintz, Levin, Cohn, Ferris,
Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	11

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,792	LIPKOWSKI ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,7,8 and 10-46* is/are pending in the application.

4a) Of the above claim(s) *15-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,7,8,10-14 and 24-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment and the Declaration of Andrzej Lipkowski filed under 37 C.F.R. 1.132 filed November 13, 2002 are acknowledged. Claims 1-3, 7-14 and 24 have been amended. Claims 4-6 and 9 have been cancelled. Claims 15-23 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention.

Objections/Rejection Withdrawn

2. In view of Applicant's amendment the following objections/rejections have been withdrawn:

a) objections to the specification, page 2, paragraph 2 of the previous Office action.
b) objections to the claims, page 2, paragraph 3 of the previous Office action.
c) rejection of claims 1-11 under 35 U.S.C. 102(b), pages 10-11, paragraph 10 of the previous Office action.
d) rejection of claims 1-11 under 35 U.S.C. 102(b), pages 12-13, paragraph 12 of the previous Office action.
e) rejection of claims1-3, 7-8 and 10-11 under 35 U.S.C. 102(b), page 7-8, paragraph 6 of the previous Office Action.

Rejections Maintained

3. The rejection under 35 U.S.C. 112, first paragraph is maintained for claims newly presented claims 1, 8 and newly presented claims 31-39 the reasons set forth on pages 2-4, paragraph 4 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with

which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention polypeptides consisting of the polypeptides SEQ ID Nos: 1, 2, 12 and 13. The specification teaches that the sequences (i.e. SEQ ID Nos: 1, and 6-11) of native substance P have been reported in various organisms, which is disclosed in Table 1 (pages 11-12). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants SEQ ID Nos: 1-2, 12 and 13 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

The skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NOs: 1 and 2 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that they have cancelled claims directed to a "sequence that is at least 50% identical to the amino acid of SEQ ID Nos: 1 or 2 and have cancelled claims directed to SEQ ID NO:12 having Xaa residues. Applicant urges that the sequence listing which was co-submitted with the application to provide the structure of each

amino acid sequence and Table 2 of the specification provides sequence data. Applicant urges that claim 8 is directed to SEQ ID NO:14 in which Xaa can be any of the 19 naturally occurring amino acids other than methionine. Applicant submit that the written description requirement had been meet.

Applicant's arguments filed November 13, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the specification has written support for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. Amended claim 8 is drawn to the composition comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell wherein the amino acid sequence of the peptide comprises SEQ ID NO:13 wherein the Xaa is not a methionine. Claim 8 (which depends from claim 1) provides a structural description of the claimed SP peptides encompassed by that claim. However, it cannot be determined by the instant specification if the claimed SP peptides of claim 8 would have the same or similar antimicobial activity as the SP peptides disclosed in SEQ ID Nos:1 and 2. Newly presented claims 31-39 are drawn to a composition comprising a fragment of a substance P peptide wherein the said fragment comprises antimicrobial activity and does not bind to a cell surface P peptide receptor. Claim 31 broadly describes a genus of substance P peptide fragments and does not provide a structure description of the peptides encompassed by the claim. Although claims 32-39 (which depend from claim 31) provide a structural description of the claimed SP fragments, it cannot be determined by the instant specification it the SP fragments of claims 32-39 have the

same or similar antimicobial activity as the SP peptides disclosed in SEQ ID Nos:1 and 2. One skilled in the art would require guidance in order to make and use the claimed SP peptides. Therefore, only SEQ ID Nos: 1 and 2 (substance P peptides) and not the full breadth of the claim (i.e. fragments of SEQ ID Nos: 1 and 2) meets the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. The Examiner agrees that the claimed invention is no longer directed to a sequence that is at least 50% identical to the amino acid of SEQ ID Nos: 1 or 2.

4. The rejection under 35 U.S.C. 112, first paragraph is maintained for claims 1, 8 and newly presented claims 31-39 the reasons set forth on pages 4-7 paragraph 5 of the previous Office Action.

The rejection was on the grounds that the claims were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID Nos: 1 and 2 does not reasonably provide enablement for the full breadth of the claims. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification is enabling only for the polypeptides of SEQ ID NOs: 1 and 2 as disclosed in the specification. The specification states that "Substance P peptides are at least 50% identical to the sequences of SEQ ID No: 1 or 2." The specification also teaches that the substance P peptides art at least 75%, 85%, 95% and 99% identical to the SEQ ID Nos. 1 or 2". The specification further states that " a conservative substitution of one amino acid for another is a replacement by an amino acid having similar chemical functional side group, e.g. replacement by another amino acid by another positively charged amino acid or replacement of a hydrophobic amino acid by another hydrophobic amino acid" (page 7). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide

determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of SEQ ID NOs: 1,2 and SEQ ID Nos: 12 and 13 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation to make and use these polypeptides is undue.

Applicant urges that screening of a limited number of compounds (encompassed by claim 8) to identify those which inhibit growth of microbial cell is not undue experimentation to one of ordinary skill in the art. Applicant urges that they have amended the claims to add a functional limitation. Applicant urges that claim 4 (that

recited % identity) has been cancelled. Applicant urges as amended the claims require a specific function (i.e. to inhibit growth of a bacterial or inhibit growth of a fungal cell) thereby eliminating inoperable embodiments. Applicant urges that the specification provides detailed guidance in the two examples enclosed regarding how to determine whether or not a composition fall within the scope of the claims.

Applicant's arguments filed November 13, 2002 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the specification is enabled for the full scope of the claims and therefore does not meet the enablement requirement as set forth in 35 U.S.C. 112, first paragraph. Amended claim 8 is drawn to the composition comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell wherein the amino acid sequence of the peptide comprises SEQ ID NO:13 wherein the Xaa is not a methionine. Claim 8 (which depends from claim 1) provides a structural description of the claimed SP peptides encompassed by that claim. However, it cannot be determined by the instant specification if the SP peptides of claim 8 would have the same or similar antimicobial activity as the SP peptides disclosed in SEQ ID Nos:1 and 2. Newly presented claims 31-39 are drawn to a composition comprising a fragment of a substance P peptide wherein the said fragment comprises antimicrobial activity and does not bind to a cell surface P peptide receptor. Claim 31 broadly describes a genus of substance P peptide fragments and does not provide a structure description of the peptides encompassed by the claim. While hybridization, recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple

substitutions or multiple modifications of other types and the positions within the amino acid sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar antimicrobial activity are limited in any peptide and the result of such modifications is unpredictable. One skilled in the art would not expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some peptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such peptides. Claims 32-39 (which depend from claim 31) provide a structural description of the claimed SP fragments. However, it cannot be determined by the instant specification whether the SP fragments of claims 32-39 would have the same or similar antimicrobial activity as the SP peptides disclosed in SEQ ID Nos:1 and 2. One skilled in the art would require guidance in order to make and use the claimed peptides commensurate in scope with the claims.

5. The rejection under 35 U.S.C. 102(b) as anticipated by Rosengurt et al, *(WO 88/07551, published October 6, 1988)* is maintained for claims 1-3, 7 10-13 and newly presented claims 24-27, 29-30 and 44-46 for the reason set forth on page 8, paragraph 7 of the previous Office action.

The rejection was on the grounds that Rosengurt et al teach a composition comprising the substance P peptide. Rosengurt et al teach that composition of their invention has the same amino acid sequence as SEQ ID NO: 1 (page 3). Rosengurt et al also teach a commercially available composition that is a structural variant of Substance P that has the amino acid sequence of SEQ ID No: 2 (page 4). Rosengurt et al teach that the antagonists or antibodies of their invention may be formulated with pharmaceutically acceptable carriers or diluents (page 6). The recitation of an "antimicrobial composition" is being viewed as a limitation of intended use. The composition of Rosengurt, et al is the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the

applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended to require a dose of substance P peptide effective to inhibit growth of either a bacterial or fungal cell. Applicant urges that Rosengurt et al fail to show or suggest any dose effective to inhibit growth of either a bacterial or a fungal cell. Applicant urges that Rosengurt et al does not anticipate the claimed invention.

Applicant's arguments filed November 13, 2002 have been fully considered but are not persuasive. The claims are drawn to a composition and kit comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell. Rosengurt et al disclose substance P peptides that have the same structures as SEQ ID Nos. 1 and 2. It is the Examiner's position that the substance P peptides as disclosed by Rosengurt et al would inherently have the same bacterial activity as the claimed substance P peptides. Applicant has provided no side-by-side comparison of the claimed substance P peptide and the substance P peptide of the prior art to show that the claimed peptide differs from that of the prior art. The claim limitation "suitable for topical administration" is being viewed as a limitation of intended use. The claim limitation "further comprising a dissolving bandage or patch" is being viewed as a limitation of design choice. Therefore, the prior art reference anticipates the claimed invention.

6. The rejection under 35 U.S.C. 102(b) as anticipated by Horig *(WO 83/01251, published April 14, 1983)* is maintained for claims 1,3, 7-8, 10-13 and newly presented claims 24-27, 29-30 and 44-46 for the reason set forth on page 9, paragraph 8 of the previous Office action.

The rejection was on the grounds that Horig teaches a composition comprising peptides or the pharmaceutically acceptable salts and agents and/or conventional pharmaceutical adjuvants (see the Abstract). The recitation of an "antimicrobial composition" is being viewed as a limitation of intended use. Horig teaches a composition that comprises the amino acid sequence of SEQ ID Nos: 1, 2 and 12. The composition of Horig is the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that no anti-bacterial activity was disclosed or suggested in Horig. Applicant urges that no effective doses of the composition comprising a substance P in a dose effective to inhibit growth of a bacterial cell are shown in Horig.

Applicant's arguments filed November 13, 2002 have been fully considered but are not persuasive. The claims are drawn to a composition and kit comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell. Horig discloses substance P peptides that have the same structures as SEQ ID No:2. It is the Examiner's position that the substance P peptides as disclosed by Horig would inherently have the same bacterial activity as the claimed substance P peptides. Applicant has provided no side-by-side comparison of the claimed substance P peptide and the substance P peptide of the prior art to show that the claimed peptide differs

from that of the prior art. The claim limitation "suitable for topical administration" is being viewed as a limitation of intended use. The claim limitation "further comprising a dissolving bandage or patch" is being viewed as a limitation of design choice. Therefore, the prior art reference anticipates the claimed invention.

7. The rejection under 35 U.S.C. 102(b) as anticipated by De Simone et al *(Journal of Clinical Lab Anal.,1989, 3(6):345-349)* is maintained for 1-3, 7-8, 10-13 and newly presented claims 24-27, 29-30 and 44-46 for the reason set forth on pages 9-10, paragraph 9 of the previous Office action.

The rejection was on the grounds that De Simone et al teach the effects of substance P on *Salmonella minnesota*. De Simone et al teach that substance P inhibits the binding of blood lymphocytes and bound-bacteria/lymphocytes. De Simone et al teach that substance is able to hamper the bacterial cytoadherence to T cells. De Simone et al discloses that substance P is involved in the mechanism of host protection against invading microorganisms (see the abstract). The recitation of an "antimicrobial composition" is being viewed as a limitation of intended use. The amino acid sequences of substance P would be inherent in the teaching of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that the claims have been amended herein to require a dose of a substance P peptide effective to inhibit growth of a bacterial cell or fungal cell. Applicant urges that De Simone et al reports that substance P inhibits binding of *Salmonella minnesota* to lymphocytes. Applicant urges that De Simone et al fail to describe or suggest a dose of substance P peptide effective to inhibit growth of a

bacterial cell or fungal cell and De Simone et al teach that the bacteria were killed prior to any exposure to a substance P peptide.

Applicant's arguments filed November 13, 2002 have been fully considered but are not persuasive. The claims are drawn to a composition and kit comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell. De Simone et al disclose substance P peptides. It is the Examiner's position that the substance P peptides as disclosed by De Simone would inherently have the same bacterial activity as the claimed substance P peptides. Applicant has provided no side-by-side comparison of the claimed substance P peptide and the substance P peptide of the prior art to show that the claimed peptide differs from that of the prior art. The claim limitation "suitable for topical administration" is being viewed as a limitation of intended use. The claim limitation "further comprising a dissolving bandage or patch" is being viewed as a limitation of design choice. Therefore, the prior art reference anticipates the claimed invention.

8. The rejection under 35 U.S.C. 102(b) as anticipated by Visser et al *(WO 92/18536, published October 29, 1992)* is maintained for 1-3, 7-8, 10-13 and newly presented claims 24-27, 29-30 and 44-46 for the reason set forth on pages 10-11, paragraph 10 of the previous Office action.

The rejection was on the grounds that Visser et al teach compositions comprising substance P (page 1 and claims 7-9, page 15). Visser et al also disclose kits containing substance P (page 7 and claims 14-18, pages 16-17). The claimed SEQ ID NO: 1 is the same as the amino acid sequence disclosed in the prior art (page 4, line 23). The composition and kit of the Visser et al is the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's composition and kit with the composition and kit of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition and kit of the prior art does not possess the same material structural and functional characteristics of the claimed composition and kit). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant urges that Visser et al shows no dose of any composition comprising substance P or its derivatives that are effective to inhibit any bacterial cell. Visser et al fail to anticipate the claimed invention. Applicant urges that Visser's dose range at the greatest concentration is merely micromolar and the claimed invention as disclosed in the specification teaches concentrations of peptides that are at least two orders of magnitude greater. Applicant urges that the kit as disclosed by Visser et al lacks Visser's label with a detectable isotope. Therefore, the claimed kit is not taught by Visser et al.

Applicant's arguments filed November 13, 2002 have been fully considered but are not persuasive. The claims are drawn to a composition and kit comprising a substance P peptide in a dose effective to inhibit growth of a bacterial cell. Visser et al

disclose substance P peptides that have the same structure as SEQ ID NO:1 and kit comprising the substance P peptides and a detectable label. It is the Examiner's position that the substance P peptides as disclosed by Visser et al would inherently have the same bacterial activity as the claimed substance P peptides. Applicant has provided no side-by-side comparison of the claimed substance peptide and kit and the substance P peptide and kit of the prior art to show that the claimed peptide and kit differs from that of the prior art. The claim limitation "suitable for topical administration" is being viewed as a limitation of intended use. The claim limitation "further comprising a dissolving bandage or patch" is being viewed as a limitation of design choice. Therefore, the prior art reference anticipates the claimed invention.

New Ground of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 24 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear as to what the applicant is referring. The first comprising should be deleted. Clarification is required.

10. Claim 25 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. The claim recites "the peptide comprises residues of 1-8 of SEQ ID NO: 2". It is unclear as to what the applicant is referring. Clarification is required.

11. Claims 29 and 30 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite "adapted for". It is unclear as to what the applicant is referring. Clarification is required.

12. Claims 32-39 are rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "a composition of 31". It is unclear as to what the applicant is referring. There is only one composition in claim 31. Clarification is required.

13. Claim 45 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. There is no antecedent basis in claim 45 for "the affected area". Clarification is required.

14. Claim 46 is rejected under 35 USC 112 second paragraph for failing to particularly point out and distinctly claim the subject matter which applicant regards as

the invention. There is no antecedent basis in claim 46 for "the kit of claim 25". Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1–2, 7, 11, 14, 24, 26, 28-34, 36, 38 and 40-46 are rejected under 35 U.S.C. 102(b) as anticipated by Maszczynska et al *(Analgesia, Vol. 3, pages 259-268, 1998)*.

Claims 1–2, 7, 14,11, 24, 26, 28-34, 36, 38 and 40-46 are drawn to an antibacterial composition comprising a substance P peptide.

Maszczynska et al teach a composition comprising 5 ng of substance P administered to mice (SP) (page 262, 1st column). Maszczynska et al teach substance P co-administered with naloxone (page 62, 2nd column). The claim limitations such as "in a dose effective to inhibit growth of a bacterial cell" and "suitable for topical administration" are being viewed as a limitation of intended use. Claim limitations such as "wherein the said dose comprises at least 44 μM of substance P peptide" or "about 44 μM to about 10 mM of substance P peptide" or "about 44 μM to about 390 μM of substance P peptide" and "further comprising a dissolving bandage or patch" are being viewed as limitations of design choice.

Since the Office does not have the facilities for examining and comparing applicant's composition with the composition of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the composition of the prior art does not possess the same material structural and functional characteristics of the claimed composition). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Status of Claims

16. No claims are allowed.

17. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308–3909.

Vanessa L. Ford
Biotechnology Patent Examiner
February 5, 2003

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600